Remarks

After entry of the amendment, Claims 35-53 are pending.

Claims 1-34 have been canceled without prejudice and New Claims 35-53 have been added in view of the Restriction Requirement, as discussed by the Examiner at Page 2 of the Office Action dated January 22, 2008. Applicants reserve the right to file one or more divisional applications to the canceled claims in view of the Restriction Requirement dated 05 September 2007.

New Claims 35-53 are supported by the specification at, for example, Paragraph Nos. 2, 29, 60, 122, 130, 136.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Rejection under 35 USC § 112, Second Paragraph

Claims 5 and 7 are rejected under 35 USC § 112, second paragraph, as being indefinite.

In view of the newly presented claims, Applicants respectfully submit that the rejection is moot and respectfully request that the rejection be withdrawn.

Rejection under 35 USC § First Paragraph

Claims 5 and 7 are rejected under 35 USC § 112, first paragraph, as lacking an adequate written description.

In view of the newly presented claims, Applicants respectfully submit that the rejection is moot and respectfully request that the rejection be withdrawn.

Obviousness-Type Double Patenting Rejection

Claims 5 and 7 are rejected on the ground of nonstatutory obviousness-type double patenting over Claims 5 and 7 of US Patent No. 6,703,359.

Applicants respectfully traverse the rejection for the following two reasons.

I. The claims recite GLP-1 (SEQ ID NO. 3) and peptides that have at least 70%, 90%, or 95% sequence identity to GLP-1 (SEQ ID NO. 3). In view of the claim amendments, the rejection is moot.

II. Contrary to the PTO's position, Paragraph No. 8 in the specification does not teach, suggest, or imply in any way that exendin is a derivative/analog of GLP-1. GLP-1 and GLP-1 analogs/derivatives are described in the specification at, e.g., Paragraph Nos. 5-7.

Exendin and exendin analogs/derivatives are described in the specification at, e.g., Paragraph Nos. 8-12.

Exendin and GLP-1 are distinct peptides encoded by different genes. *See* Chen et al, *The Journal of Biological Chemistry*, 272(7):4108-4115 (February 14, 1997) (hereafter "Chen"); and Nielsen et al, *Current Opinion in Investigational Drugs*, 4(4):401-405 (2003) (hereafter "Nielsen"). Chen is attached hereto as Exhibit A. Nielsen is attached hereto as Exhibit B.

Chen studied the genetic relationship between exendin-4 and GLP-1 by analyzing the structure and expression of proglucagon mRNAs in *Heloderma suspectum* to determine whether exendin-4 was the reptilian equivalent of GLP-1 (Chen at page 4108, right column bridging to page 4109, left column). At page 4114, right column bridging to page 4115, Chen states:

> Although exendin 4, as isolated and sequenced from *H. suspectum* venom, is 52% identical to mammalian GLP-1, the cloning of lizard proglucagon cDNAs demonstrated that the sequence of exendin 4 is not encoded by lizard preproglucagon, and lizard exendin 4 is now shown to be only 45% identical to lizard GLP-1. …exendin 4 and lizard GLP-1 are unique peptides encoded by different genes.
>
> Lizard GLP-1 shares 90 and 84% identity to chicken and human GLP-1, respectively, and lizard glucagon shares 92 and 97% identity to chicken and human glucagon, respectively….
>
> Taken together, the demonstration that exendin 4 is encoded by a lizard gene distinct from proglucagon in the lizard raised the possibility that other species, perhaps mammals, may also contain distinct exendin genes. ….

Chen teaches that exendin and GLP-1 are distinct peptides encoded by different genes. Lizard GLP-1 (not an exendin) is homologous to mammalian GLP-1. *See also* Nielsen at page 401, right column, last two paragraphs ("Exendin-4 has a 53% amino acid sequence overlap with mammalian glucagon-like peptide-1 (GLP-1). However, exendin-4 is transcribed from a distinct gene, not the Gila monster homolog of the mammalian proglucagon gene from which GLP-1 is expressed.")

In addition to the clear teachings in the specification, the literature teaches and the skilled artisan would recognize that exendin is not a derivative/analog of GLP.

For the above reasons, Applicants respectfully request that this obviousness-type double patenting rejection be withdrawn.

Conclusion

Applicants respectfully request an early and favorable consideration and allowance of Claims 35-53.

Respectfully submitted,

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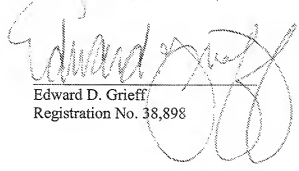

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